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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,730	01/17/2002	Brooks Edwards	9550-001-27	2580

7590 12/10/2004

Supervisor, Patent Prosecution Services
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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/046,730

Applicant(s)

EDWARDS ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-22,24-26 and 28-58 is/are pending in the application.
- 4a) Of the above claim(s) 32-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-22,24-26,28-31 and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1) Pending claims 1, 3-9, 11-22, 24-26, 28-31 and 53-58 have been examined on the merits in this Office action.

2) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) Claims 1, 3-9, 11-22, 24-26, 28-31 and 53-58 are again rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bronstein et al (US 5,849,495) for the reasons stated in paragraph **12)** of the May 03, 2004 Office action.

Applicants' arguments filed September 03, 2004 have been fully considered but they are not persuasive. At page 18 of the Remarks, applicants state that Bronstein et al "describes coating a membrane with copolymers containing pendant onium groups, but does not teach or suggest attaching probes to the membrane" (emphasis added). This statement is inconsistent, however, with the description of Bronstein et al which does, in fact, describe probes attached to the surface of the solid support. Bronstein et al, at col. 14, lines 3-8 describes "kits" with a polymeric onium compound-containing solid surface which are "used to determine the presence or concentration of any biological substance, including RNA, DNA, proteins and haptens" and "used for detections performed on membranes such as Western, Southern, Northern blotting and DNA sequencing, and can also be used for solution-phase assays". Clearly, these surfaces have biomolecules attached which are complementary to (i.e. are the corresponding specific binding partners for) the analytes to be determined. Col. 1, line 65 – col. 2, line 22 of Bronstein et al further describes the state of the art with regard to the use of dioxetane-based chemiluminescent assays, the same technology of the instant invention (see the instant specification at page 7, the last paragraph); this section of the reference describes the attachment of one

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member of a specific binding pair member to a solid support and the use of this solid support to detect the corresponding specific binding pair member analyte. The additional onium polymer component is described by both Bronstein et al and the instant specification as a chemiluminescence enhancer.

Applicants' attempt to make a distinction between a "biopolymer target" and a "probe" being attached to the solid support is not understood (Remarks, page 18; second full paragraph). Consistent with the discussion provided by applicants at page 16, the last paragraph of the Remarks, one skilled in the art would recognize that either a "target" (one member of a specific binding pair) or a "probe" for the target (the corresponding specific binding pair member) could be attached to the solid support, i.e. the term "target" and the term "probe" could be used to define either member of a specific binding pair.

5) Claims 1, 3, 8, 22-24 and 53-58 are again rejected under 35 U.S.C. 102(b) as being anticipated by Bronstein et al (US 5,336,596) for the reasons stated in paragraph **13)** of the May 03, 2004 Office action.

Applicants' attempt to make a distinction between a "biopolymer target" and a "probe" being attached to the solid support is not understood (Remarks, the paragraph bridging pages 18 and 19). Consistent with the discussion provided by applicants at page 16, the last paragraph of the Remarks, one skilled in the art would recognize that either a "target" (one member of a specific binding pair) or a "probe" for the target (the corresponding specific binding pair member) could be attached to the solid support, i.e. the term "target" and the term "probe" could be used to define either member of a specific binding pair. In claim 3, of the patent the "analyte" could be called the "probe" while the corresponding "antibody" could be called the "biopolymer target" or the nomenclature of the two terms could be reversed; in either case, the "antibody" and "analyte" are the two members of a specific binding pair.

6) THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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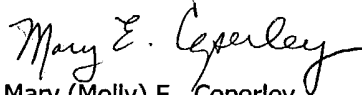
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 07, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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